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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,745	08/17/2001	Todd Hockstra	HOE002USPT01	4601

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THOMAS E. FISHER
WATTS HOFFMANN CO., L.P.A.
1100 SUPERIOR AVENUE
SUITE 1750
CLEVELAND, OH 44114

EXAMINER

PARADISO, JOHN ROGER

ART UNIT	PAPER NUMBER
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3721

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/932,745

Applicant(s)

HOEKSTRA, TODD

Examiner

John R. Paradiso

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19-23, 38, 39, 46, 47 and 50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19-23, 38, 39, 46, 47 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-5, 7-16, 19-23, 38-39, 46-47, and 50-52 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WEISS ET AL (US 6117505) in view of OTSU ET AL (US 6449925).

WEISS ET AL discloses an article comprising a longitudinally continuous web comprising two superimposed layers: a first layer (11, 12) that is a gas-permeable microbial barrier layer and a second layer (13) that is a thermoplastic gas impermeable layer. (See WEISS ET AL col. 6:3-31, and Fig. 1-2.)

WEISS ET AL does not disclose perforations / lines of weakness in the first and second layers at the same positions. WEISS ET AL implies, but does not specifically disclose the layers being formed from continuous webs.

OTSU ET AL (US 6449925) discloses a longitudinal web comprising a first layer and a second layer, with the first and second layer superimposed upon one another and longitudinally spaced lateral lines of weakness / perforations made in both layers at the same points so that the packages can be separated. (See OTSU ET AL col. 3:1-7 and Figs. 1 and 3.)

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to make longitudinally spaced lateral lines of weakness / perforations, as taught by OTSU ET AL, in the invention of WEISS ET AL in both layers at the same points in order to provide a convenient method for separating the bags from one another when needed for use.

The recitations in claims 1 and 14 of "to be sterilized by sterilizing gas passed through the permeable layer", the recitation in claim 38 of "permitting the passage of a sterilizing gas", and the recitation in claim 50 of "may be sterilized and subsequently accessed with out fear of contamination by residues" are given little, if any, patentable weight since they amount to an intended use of the claimed article and it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Further, WEISS ET AL is capable of such use, if desired.

Regarding claims 2 and 3, Examiner notes that lines of separation and lines of perforation are art-recognized equivalents and it would have been obvious to one of ordinary skill in the art at the time the invention was made to make either lines of perforation or lines of weakness in either layer of the combination of WEISS ET AL and OTSU ET AL, depending on which was more convenient for a user when it was desired to separate the formed packages.

Regarding claims 7, 8, and 18, WEISS ET AL discloses a microbe-impervious peelable seal (B) near the lines of weakness / perforations (WEISS ET AL col 8:1-3).

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Regarding claims 10, 20, and 51, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the choice of a spunbonded olefin as the first layer, since this material is well known in the art of packaging and since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 11 and 21, the thermoplastic layer disclosed by WEISS ET AL is transparent.

Regarding claim 13, 23, and 52, OTSU ET AL does not disclose the specifics of the claimed perforations regarding area ratios and perfs per cm., however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the perforations in the combination of WEISS ET AL and OTSU ET AL of the claimed dimensions in order to achieve optimum perforation ease and utility, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claim 15, OTSU ET AL discloses forming the superimposed web layers into a roll (10) (OTSU ET AL Fig. 3)

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3. Claims 6 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WEISS ET AL in view of OTSU ET AL as applied to claims 5 and 16 above, and further in view of McINTOSH, SR. ET AL (US 4226410).

McINTOSH, SR. ET AL discloses a web of material (16) which, after processing and perforating, is folded in a pleated stack (Fig. 1a)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to fold the finished articles in the combination of WEISS ET AL and OTSU ET AL in a pleated stack, as taught by McINTOSH, SR. ET AL, in order to more easily package the stack in standard boxes.

Response to Arguments

4. Applicant's arguments filed 2/17/2004 have been fully considered but they are not persuasive.

5. Applicant states on page 2 of his Response that "We submit a rejection on Cronauer in view of Weiss et al ... is more to the point."

However, the possibility of other rejections in no way affects the rejection of the claims detailed above.

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6. Applicant states on page 2 of his Response that "Applicant's product is new and unobvious because he has made an enabling disclosure of how to produce what was not made before, perhaps because no one thought it possible."

However, this argument amounts merely to an allegation of patentability and a conjecture of why the article was not seen elsewhere in the marketplace, not a refutation or argument of the merits of the rejection.

7. Applicant states on page 2 of his Response that "At least as best we can determine it was applicant who determined that suitable lines of weakness could be made to enable the production of a sterilizable bag product suitable for use on one of Automated's machines such as the H 100 and competitive products."

However, the rejection above clearly details how the claimed invention would be unpatentable over WEISS ET AL in view of OTSU ET AL, as described above.

Additionally, Examiner points out that the claims in the instant application are to an article and therefore the intended use, such as "for use on one of Automated's machines such as the H 100 and competitive products" is immaterial.

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8. Applicant states on page 2 of his Response that "he [Applicant] approached a dozen ... companies licensed by DuPont to make sterilizable packages utilizing the Tyvek medical grade product. Not one of the licensees was willing to attempt to produce Applicant's product disclosed and claimed here."

However, the fact that other manufacturers would or would not manufacture a prototype for Applicant is immaterial to the rejection. The only pertinent fact of the rejection is the disclosures of the references detailed in paragraphs 2-3 above and that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the references as explained above.

9. Applicant states on pages 2-3 of his Response that "the art does [not] suggest sterilizable bags of the type disclosed and claimed by Applicant connect[ed] by perforations or other lines of weakness for facile separation. Rather a user either uses individual sterilizable bags or utilizes sheets with multiple bags connected together. A user of such a sheet must cut the bags apart with scissors..."

However, OTSU ET AL clearly shows bags connected by lines of perforations (see the dashed lines in OTSU ET AL Fig. 1).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

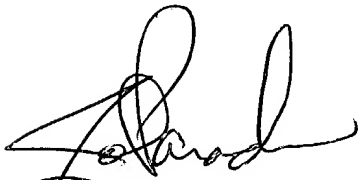
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Paradiso. The examiner can normally be reached Monday-Friday, 9:30 p.m. – 6:00 p.m. (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada, can be reached at the number listed below.

Any inquiry of a general nature or relating to the status of this application should be directed to the 3700 Technology Center Receptionist.



Examiner John Paradiso: (703) 308-2825



SCOTT A. SMITH
PRIMARY EXAMINER

May 12, 2004

Additional Phone Numbers:

Supervisor Rinaldi Rada: (703) 308-2187
TC 3700 Receptionist: (703) 308-1148
Customer Service: (703) 306-5648
Fax (directly to Examiner) (703) 746-3253
Fax (Official): (703) 872-9306